

REMARKS

All of the rejections of record have been reversed by the Board of Patent Appeals and Interferences, and according to 37 C.F.R. §41.54 the proceeding will be returned to the examiner to carry into effect the decision. Applicants take this opportunity prior to further action to amend the claims to add additional dependent claims, and to file supplemental Information Disclosure Statement forms.

The Board agreed with Applicants that the specification's written description supports proteins comprising the entire extracellular domain of the human p75 TNF Receptor and soluble TNF-binding fragments thereof. New claims 145-148 are drawn to a protein consisting essentially of the extracellular region of the human p75 TNF Receptor and all of the domains other than the first domain of a human IgG1 heavy chain, as well as pharmaceutical compositions thereof. No new matter is added by these claims.

Support for the recitation of "extracellular region" is found throughout the specification. The "extracellular part" and "extracellular region" of a TNF binding protein are disclosed in the examples, which are explicitly defined as illustrative of the invention. See page 20, lines 27-30. See, for example, the disclosure at page 37, lines 15-18 ("extracellular part"), and page 42, lines 5-7 ("extracellular region"), which use the 55 kD TNF binding protein as the exemplary TNF binding protein. Applicants disclose throughout the specification, at almost every instance, that the exemplary embodiments relate to both of the 55 kD and 75 kD TNF binding proteins that are the subject of the application. See, e.g., page 9, line 19 through page 10, line 10; page 14, lines 32-36; and page 35, lines 22-23 ("[e]ssentially analogous techniques" used for p75 and p55 TNFR).

Patentability of the new claims is further supported by scientific results presented herewith in the Declaration of Taruna Arora under 37 C.F.R. 1.132 (item E3 in the accompanying Information Disclosure Statement forms). These results confirm Applicants' prior evidence that an embodiment within the scope of Applicants' claims, etanercept, shows unexpected properties when compared to TNF-binding proteins that fall outside of the scope of Applicants' claims. This embodiment was compared to two different anti-TNF antibodies

and two different fusion proteins, Delta 57 and Protein 3.5D. Delta 57 and Protein 3.5D contain only a portion of a hinge domain- they are missing the first several amino acids of this domain - and thus do not comprise “all of the domains of the constant region of a human immunoglobulin IgG heavy chain other than the first domain”. In these experimental results, the two anti-TNF immunoglobulins and the Delta 57 and Protein 3.5D fusion proteins did not exhibit the same, consistent, and surprising lack of complement mediated cytotoxicity and antibody dependent cellular cytotoxicity that was shown by etanercept.

Applicants have previously drawn the Examiner’s attention to co-pending application serial no. 08/444,791 which claims common priority with the present application. Although Applicants are informed that the Examiner has access to the electronic file of this application, for the Examiner’s convenience, copies of the two most recent Office Actions from this co-pending application are supplied and listed on the attached Information Disclosure Statement forms as items E1 and E2.

Copies of items C1, and D1-D5 listed on the attached Information Disclosure Statement forms are supplied herewith. The Examiner is requested to acknowledge consideration of these items as well as items E1-E3 by initialing the enclosed forms. The Director is hereby authorized to charge any requisite fees to our Deposit Account No. 13-2855, under Order No. 01017/40451B.

Application No.: 08/444,790

Docket No.: 01017/40451B

CONCLUSION

Applicants believe all pending claims are in condition for allowance. If further discussion or amendments would expedite allowance of the claims, the Examiner is asked to contact the undersigned at the number below.

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Respectfully submitted,

By /Li-Hsien Rin-Laures 33,547/

Li-Hsien Rin-Laures

Registration No.: 33,547

MARSHALL, GERSTEIN & BORUN LLP

233 S. Wacker Drive, Suite 6300

Sears Tower

Chicago, Illinois 60606-6357

(312) 474-6300

Attorney for Applicant